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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:
Alexandros MAKRIYANNIS et al

Serial No. 09/701,989

Examiner: C. T. Ostrup

Filing Date: January 29, 2001

Group Art Unit: 1614

For: INHIBITORS OF ANANDAMIDE TRANSPORTER AS ANALGESIC AGENTS

Commissioner for Patents
United States Patent and Trademark Office
Washington, DC 20231

Sir:

RESPONSE TO RESTRICTION/ELECTION REQUIREMENT

The November 1, 2002 Office Communication alleges that the above-referenced application contains multiple inventions in Group I (claims 1-7, drawn to a method of using a composition) and Group II (claims 8-14, drawn to a composition). As support for this restriction the Office Communication states:

The inventions listed as Groups I and II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same or corresponding special technical features. for the following reasons: Applicant is referred to Annex B of Appendix A1 of the MPEP (Administrative Instructions Under the PCT, "Unity of Invention"). Unity "exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding claimed technical features. The expression "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions as a whole, makes over the prior art." (Rule 13.2).

Whether a given technical feature defines a contribution may be reconsidered *a posteriori* on the basis of the results of the search of the prior art (subsections c(ii) and c(iii); for Markush groups, subsection f(v) specifies that "when dealing with alternatives if it can be shown that at least one Markush group alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner."

MPEP Appendix A1, Annex B, subsection c is concerned with unity of invention between an independent claim and claims dependent therefrom. Subsection c(ii) concerns whether an inventive link remains between an independent claim and claims dependent

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therefrom if the independent claim does not avoid the prior art. Subsection c(iii) merely states that the initial determination of unity of invention between an independent claim and its dependent claims may be reconsidered on the basis of a prior art search. The present restriction is not between an independent claim and claims dependent therefrom. Rather the present restriction is between two independent claims. Thus, MPEP Appendix A1, Annex B, subsection c provides no support for the present restriction.

MPEP Appendix A1, Annex B, subsection f is directed to:

(f) **'Markush Practice.'** The situation involving the so-called 'Markush practice' wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

The present restriction is not between members of a Markush group within a single claim. Rather the present restriction is between two independent claims. Thus, MPEP Appendix A1, Annex B, subsection f provides no support for the present restriction.

MPEP Appendix A1, Annex B, subsection f(i) states:

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) all alternatives have a common property or activity, and
- (B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or
- (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

Applicants' claims include compounds having a common property or activity of inhibiting transport of anandamide. Further, Applicants' compounds share "significant structural elements" in the X and Y moieties and substantially all of the Z moiety. Arguendo, under the Office Communication's interpretation of MPEP Appendix A1, Annex B, subsection f, Applicants' claims are of a similar nature under subsection f(i)(A) and f(i)(B)(1), have a special technical feature under Rule 13.2 and therefore have unity of invention.

More related to the Applicants' pending claims is MPEP, Appendix A1, Annex B, subsection e, which states:

(e) **Combinations of Different Categories of Claims.** The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

Claim 1 is an independent claim directed to a method of inhibiting transport of anandamide . . . comprising administering to the individual or animal a therapeutically effective amount of a compound represented by a specified formula. Claim 8 is an independent claim directed to a compound sharing X, Y and virtually all of the Z moieties with the compound recited in claim 1. Thus pending claims 1 and 8 appear to be allowable under MPEP, Appendix A1, Annex B, subsection e(i).

Applicants respectfully traverse the above restriction requirement based on MPEP, Appendix A1, Annex B, subsections c(ii), c(iii) and f(v) and respectfully assert that this restriction requirement should be withdrawn or supported in the face of MPEP, Appendix A1, Annex B, subsections f(i) and e(i).

The November 1, 2002 Office Communication also, confusingly, appears to impose an election of species. The Office Communication first states that: "[t]his application contains claims directed to more than one species of the generic invention" and alleges that "these species are deemed to lack unity of invention . . ." See Office Communication page 3. The Office Communication goes on to state:

The species are as follows: Claims 1-14 relate to so many possible compounds and the compounds of claims 7 and 14 do not even relate to the generic structure of claims 1 and 8, from which they depend . . ."

Thus, applicants are required, in reply to this action, to elect a single species (one compound which is clearly identifiable) to which the claims will

be restricted if no generic claim is finally held to be allowable. . . .

The claims are deemed to correspond to the species listed above in the following manner: Group I and Group II both correspond to the same species, however, the search and examination of the elected species will only be searched and examined to the extent it reads on the elected group.

The species listed above do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding technical features for the following reasons: The special technical feature is the generic compound of claim 1. However, the compound of claim 1 is not special. As discussed above . . . at least one claimed species is not novel over the prior art.

Applicants' claims include compounds having a common property or activity of inhibiting transport of anandamide. Further, these compounds share "significant structural elements" in the X and Y moieties and substantially all of the Z moiety. Under MPEP Appendix A1, Annex B, subsection f, Applicants' claims are of a similar nature under subsection f(i), have a special technical feature under Rule 13.2 and therefore have unity of invention.

Further, Applicants note that MPEP Appendix A1, Annex B, subsection f(v) does not appear to state that a lack of novelty for one claim member must give rise to a lack of unity. Rather, subsection (v) merely states that a lack of novelty for one claim member allows reconsideration of the question of unity under the subsection (i) criteria. Applicants respectfully traverse the statement that their claims lack unity of invention and assert that this statement should be withdrawn or supported in the face of MPEP, Appendix A1, Annex B, subsection f.

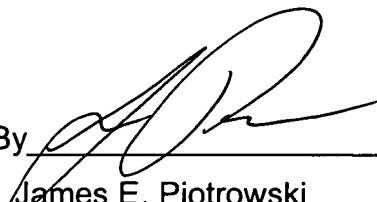
If the Examiner is attempting to impose a provisional election under MPEP §803.02, Applicants respectfully request that the next Office communication indicate that the assertion of lack of unity is withdrawn and a provisional election imposed in its place.

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In order to strictly comply with the above Restriction Requirement, Applicants' provisionally elect, with traverse, the invention of Group 1, including claims 1-7, drawn to a method of using a composition. Under this provisional election, claim 1 is generic and claims 2-7 read on claim 1.

In order to strictly comply with an election requirement under MPEP §803.02, Applicants' provisionally elect, with traverse, the following species: Claim 1 wherein the X moiety terminal radical is biphenyl; Y is -NH-C(O)-; and Z is cyclic glycerol.

Respectfully submitted,
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